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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/857,214 | 06/22/2001 | Hayao Tanaka | 210131US0PCT | 5190 |

22850 7590 04/20/2004

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| EXAMINER | |
|---|---|
| AUGHENBAUGH, WALTER | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1772 | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/857,214 | TANAKA, HAYAO | |
| | Examiner | Art Unit | |
| | Walter B Aughenbaugh | 1772 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6,7 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2003 has been entered.

### *Acknowledgement of Applicant's Amendments*

2. The amendments made to claim 12 in the Amendment filed October 23, 2003 (Amdt. B) have been received and considered by Examiner.

3. The cancellation of claims 4 and 5 in Amdt. B has been acknowledged by Examiner.

### *WITHDRAWN REJECTIONS*

4. The 35 U.S.C. 112, second paragraph rejection of claims 4 and 5 made of record in paragraph 16 of Paper 10 has been withdrawn due to the cancellation of claims 4 and 5 in Amdt. B.

5. The 35 U.S.C. 103 rejections made of record in paragraphs 17-20 of Paper 10 have been withdrawn due to the amendments (and claim cancellations) made in Amdt. B.

### *REPEATED REJECTIONS*

6. The 35 U.S.C. 112, second paragraph rejection of claim 7 that was repeated in paragraph 15 of Paper 10 has been repeated for the reasons previously made of record.

7. The 35 U.S.C. 112, second paragraph rejection of claim 12 made of record in paragraph 16 of Paper 10 has been repeated for the reasons previously made of record, although the basis of

rejection regarding the "polyoxy...methacrylate" term, the "phopholipid" term and the "at least" recitation has been withdrawn due to the deletion of these terms (and recitation) from the claim in Amdt. B.

## *NEW REJECTIONS*

### *Claim Rejections - 35 USC § 103*

8. Claims 6, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox in view of Waki et al. and in further view of Applicant's admitted prior art.

In regard to claim 12, Fox teaches a reaction well with a bottom wall that has an inner surface that is hydrophilic and side walls that have hydrophobic inner walls (col. 2, lines 15-29). Fox teaches that the reaction well is for conducting an immunogenic reaction (col. 3, lines 22-25); therefore, Fox teaches a container for an immunoassay. Fox teaches that the bottom of the well is coated with a hydrophilic material or the inner surface 32 of the bottom wall 28 is made from a hydrophilic plastic (col. 2, lines 25-30 and Figure 4); Fox therefore teaches that the inner surface of the container is formed from or coated with a hydrophilic polymer. The inner surface of the container of Fox necessarily would contact an immunoassay specimen. The hydrophilic polymer is necessarily insoluble in water; the inner surface of a container for an immunoassay, or a container for any application that requires the container to hold any aqueous liquid, is necessarily formed of a polymer that is insoluble in water so that the polymer does not dissolve in the solution the container contains.

Fox fails to teach that the hydrophilic polymer is a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit and that the saturation adsorption

amount, on the inner surface of the container, of molecules used for the assay is $1 \times 10^{-1}$ pmol/cm$^2$ or less.

Waki et al., however, disclose that copolymers containing 2-methacryloyloxyethylphosphorylcholine are suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers (col. 1, lines 16-25, 28-44 and 54-59). Therefore, one of ordinary skill in the art would have recognized to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Fox since such copolymers are notoriously well known as suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Fox since such copolymers are notoriously well known as suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

In further regard to claim 12 and also in regard to claim 7, since Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm$^2$ or more and that the adsorption amount varies in

accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Furthermore, Waki et al. disclose that copolymers containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit lack biomaterial (such as protein) absorbing property (col. 1, lines 16-23 and 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer taught by Fox and Waki et al., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitations "for an immunoassay" and "which is to contact a specimen for immunoassay", are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The limitation "coated with" has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claim 6, Fox teaches that an aqueous solution spread relatively evenly across the bottom of the wells in all samples tested (col. 8, lines 20-23); therefore, the contact angle of

the aqueous solution on the bottom of the well approaches a contact angle of zero, a condition which reads on the claimed contact angle value of "1° or less".

9. Claims 6, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. in view of Waki et al. and in further view of Applicant's admitted prior art.

Levy et al. teach a hydrophobic cuvette, the inner surface of which is coated with a hydrophilic polymer (col. 4, lines 41-45). The inner surface of the container of Levy et al. necessarily would contact an immunoassay specimen. The hydrophilic polymer is necessarily insoluble in water; the inner surface of a container for any application that requires the container to hold any aqueous liquid is necessarily formed of a polymer that is insoluble in water so that the polymer does not dissolve in the solution the container contains.

Levy et al. fails to teach that the hydrophilic polymer is a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit and that the saturation adsorption amount, on the inner surface of the container, of molecules used for the assay is $1 \times 10^{-1}$ pmol/cm$^2$ or less.

Waki et al., however, disclose that copolymers containing 2-methacryloyloxyethylphosphorylcholine are suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers (col. 1, lines 16-25, 28-44 and 54-59). Therefore, one of ordinary skill in the art would have recognized to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Levy et al. since such copolymers are notoriously well known as suitable for use as a biocompatible

material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Levy et al. since such copolymers are notoriously well known as suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

In further regard to claim 12 and also in regard to claim 7, since Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-$cm^2$ or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Furthermore, Waki et al. disclose that copolymers containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit lack biomaterial (such as protein) absorbing property (col. 1, lines 16-23 and 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer taught by Levy et al. and Waki et al., since it has been held that discovering an optimum value of a result effective variable involves only

routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitations "for an immunoassay" and "which is to contact a specimen for immunoassay", are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The limitation "coated with" has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claim 6, the contact angle between the inner surface of the container made of a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit and water is necessarily 1° or less since a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit is an ultra-hydrophilic polymer as claimed by Applicants, and since the specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

10. Claims 6, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler in view of Waki et al. and in further view of Applicant's admitted prior art.

Buechler teaches a diagnostic device with time gate 5 leading into reaction chamber 4 (col. 7, lines 41-42 and Figure 1B) for an immunoassay (col. 8, line 39). The time gate is a capillary channel with hydrophobic surfaces (col. 7, lines 58-67) and serves as a barrier to a hydrophilic liquid (col. 7, lines 53-58). The hydrophobic barrier is changed to a hydrophilic

zone when a certain component of the reaction mixture binds to the hydrophobic capillary channel walls (col. 8, lines 7-10). Buechler teaches that this component is chosen from various proteins, polypeptides or polymers (col. 8, lines 17-23). The hydrophobic inner surface of the capillary channel is therefore coated with a hydrophilic polymer to enable the hydrophilic reaction mixture to flow through the capillary. The inner surface of the capillary channel of Buechler necessarily contacts an immunoassay specimen.

Buechler fails to teach that the hydrophilic polymer is a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit and that the saturation adsorption amount, on the inner surface of the container, of molecules used for the assay is $1 \times 10^{-1}$ $pmol/cm^2$ or less.

Waki et al., however, disclose that copolymers containing 2-methacryloyloxyethylphosphorylcholine are suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers (col. 1, lines 16-25, 28-44 and 54-59). Therefore, one of ordinary skill in the art would have recognized to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Buechler since such copolymers are notoriously well known as suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit as the hydrophilic polymer of Buechler since such copolymers are notoriously well known as suitable for use as a biocompatible material for biocompatible surfaces for various bio-related purposes due to the high biocompatibility of these copolymers and due to the lack of biomaterial (such as protein) absorbing property of these copolymers as taught by Waki et al.

In further regard to claim 12 and also in regard to claim 7, since Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm$^2$ or more and that the adsorption amount varies in accordance with the concentration of a solution containing such molecules and the contact area between the molecules and the container (page 6, line 26-page 7, line 6 of applicants' specification). Furthermore, Waki et al. disclose that copolymers containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit lack biomaterial (such as protein) absorbing property (col. 1, lines 16-23 and 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal type of molecule, and the optimal concentration range of the particular molecule in solution, in order to achieve the claimed saturation adsorption amount for the inner surface of the container formed from or coated with the hydrophilic polymer taught by Buechler and Waki et al., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The recitations "for an immunoassay" and "which is to contact a specimen for immunoassay", are intended use phrases that have not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). The limitation "coated with" has not been given patentable weight since the method of forming the container is not germane to the issue of patentability of the container itself.

In regard to claim 6, the contact angle between the inner surface of the container made of a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit and water is necessarily 1° or less since a copolymer containing a 2-methacryloyloxyethylphosphorylcholine polymer subunit is an ultra-hydrophilic polymer as claimed by Applicants, and since the specification defines "an ultra-hydrophilic polymer" as a polymer that forms an inner surface of the container having a contact angle between the surface and water of 1° or less (page 12, lines 5-10).

***ANSWERS TO APPLICANT'S ARGUMENTS***

11. Applicant's arguments on pages 4-5 of Amdt. B regarding the 35 U.S.C. 103 rejections of record in Paper 10 are moot due to the withdrawal of the 35 U.S.C. 103 rejections of record in Paper 10 in this Office Action.

12. Applicant's arguments on pages 5-6 of Amdt. B regarding the 35 U.S.C. 112 rejection of claim 7 repeated in paragraph 15 of Paper 10 and of claim 12 made of record in paragraph 16 of Paper 10 have been fully considered but are not persuasive. Applicant argues that "the saturation adsorption amount is, in fact, a function of the container", but since there are other determining

factors involved as discussed in paragraph 16 of Paper 10, the claimed saturation adsorption amount is meaningless without qualification or quantification (where appropriate) of the particular determining factors most recently discussed in paragraph 16 of Paper 10, thus rendering the claim indefinite. In response to Applicant's argument that the specification "clearly provides guidance for the selection of the criteria alluded to by the Examiner", the limitations on which the Applicant relies are not stated in the claims. It is the claims that define the claimed invention, and it is the claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.*, 7 USPQ2d 1064. This 35 U.S.C. 112 rejection was not made "because the Examiner merely wants the Applicant to improve the clarity or precision of the language used" as Applicant suggests, but because the claim is incomplete in regard to the determining factors that are necessary to distinctly claim the subject matter which Applicant regards as the invention.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,040,415 to Arimori et al., US 6,258,371 to Koulik et al. and US 6,583,251 to Chaikof et al.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
04/16/04 WBA

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

4/16/04